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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BERTAGNA, ANGELA MARIE	
ART UNIT	PAPER NUMBER
1637	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/773,761	ERLANDER ET AL.	
	Examiner	Art Unit	
	Angela M. Bertagna	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2010 and 21 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,16,18-23,25,27-31,52-55,62,63,69 and 71-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,16,18-23,25,27-31,52-55,62,63,69 and 71-73* is/are rejected.

7)☒ Claim(s) *14 and 23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/7/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. Applicant's response filed on July 21, 2010 is acknowledged. Claims 14, 16, 18-23, 25, 27-31, 52-55, 62, 63, 69, and 71-73 are currently pending. In the response, Applicant amended claims 14, 16, 23, 25, 52-55, 62, 63, and 69, canceled claims 6-8, 10-13, 15, 24, 32-38, 42, 49, 50, 56-61, 67, 68, and 70, and added claims 71-73.

The following include new grounds of rejection. Any previously made rejections or objections not reiterated below have been withdrawn. Applicant's arguments filed on March 21, 2010 and entered on July 21, 2010 have been fully considered, and they were persuasive in part (see the "Response to Arguments" section). Since the rejection made previously under 35 U.S.C. 112, first paragraph (enablement) has been modified in ways that were not entirely necessitated by Applicant's amendment, this Office Action is made **NON-FINAL**.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original non-provisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35

U.S.C. 112. See Transco Products, Inc. v. Performance Contracting, Inc., 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

In this case, the disclosure of the prior-filed application, Provisional Application No. 60/504,087, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for all of the pending claims in the instant application. The '087 application does not provide adequate support for the requirement in all of the instant claims to determine the ratio of HoxB13 and IL17BR RNA expression levels. Also, neither the '087 application nor prior-filed Application Serial No. 10/727,100 discusses the aromatase inhibitors recited in all of the pending claims. Finally, as discussed in greater detail in section 5 below, neither of the prior-filed applications (*i.e.*, non-provisional Application Serial No. 10/727,100 and Provisional Application No. 60/504,087) provide adequate support for determining the average HoxB13:IL17BR mRNA expression level ratio using the average HoxB13 and IL17BR mRNA expression levels in ER+ breast cancer cells obtained from human breast cancer patients that respond to treatment with an antiestrogen agent and from human breast cancer patients that do not respond to treatment with the antiestrogen agent as required by all of the pending claims in the instant application. Accordingly, benefit of the prior-filed '087 and '100 applications has not been granted, and the filing date of the instant application, (**February 6, 2004**) has been used for prior art purposes.

Information Disclosure Statement

3. Applicant's submission of an Information Disclosure Statement on May 7, 2010 is acknowledged. A signed copy is enclosed.

Claim Objections

4. Claims 14 and 23 are objected to because of the following informalities: The full names of the HoxB13 and IL17BR genes should be written out in the claims before the abbreviated forms are used to ensure clarity. Also, the phrase "to determine outcome of a human subject" in claim 14 appears to be missing words, such as "a clinical", before the word "outcome".

Appropriate correction is required.

Claim Rejections - 35 USC § 112, 2nd paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25, 27-31, 69, and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25, 27-31, 69, and 71 are indefinite, because they depend directly or indirectly from claim 24, which has been canceled. For examination purposes, the claims have been considered to depend from claim 23.

Claim Rejections - 35 USC § 112, 1st paragraph (New Matter)

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14, 16, 18-23, 25, 27-31, 52-55, 62, 63, 69, and 71-73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

MPEP 2163.03 states, "An amendment to the claims or the addition of a new claim must be supported by the description of the invention in the application as filed." *In re Wright*, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989). MPEP 2163.05 states, "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement." *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).

These claims are drawn to methods of using the ratio of HoxB13:IL17BR mRNA expression levels measured in a sample of breast cancer cells obtained from an estrogen receptor positive (ER+) breast cancer patient to assess the subject's responsiveness to an aromatase inhibitor, such as anastrozole, letrozole, or vorozole, and, thereby, predict the subject's risk of cancer recurrence. The claims recite that the HoxB13:IL17BR mRNA expression level ratio is compared to an average HoxB13:IL17BR mRNA expression level ratio to assess the subject's responsiveness to the aromatase inhibitor and predict the risk of cancer recurrence. The claims further recite that the average HoxB13:IL17BR mRNA expression level ratio is determined from the average HoxB13 and IL17BR mRNA expression levels in ER+ breast cancer cells obtained from human breast cancer patients that responded to treatment with the aromatase inhibitor and from human breast cancer patients that did not respond to treatment with the aromatase inhibitor.

Applicant states that the limitation finds support throughout the application as filed and, in particular, at Figures 3, 6, and 7 of Application Serial No. 10/727,100, to which the instant application claims priority and which has been expressly incorporated by reference.

The original disclosure, including the disclosure of the incorporated '100 application, has been carefully reviewed, but it does not appear to provide adequate support for the claimed method of determining the average HoxB13:IL17BR mRNA expression level ratio. The instant application and the incorporated '100 application appear to provide proper support for the following (see Figure 2a-2d and Examples 3-4 of the instant application; see also Figures 3, 6, and 7 of the '100 application, which were cited by Applicant as providing support for the claimed limitation): (i) measuring HoxB13 & IL17BR mRNA expression levels in samples obtained from a cohort or "training set" of breast cancer patients known to be "tamoxifen responders" and "tamoxifen non-responders" and determining the HoxB13:IL17BR ratio for each sample, (ii) conducting a logistic regression analysis to determine a cutoff point that accurately classifies the patients in the cohort as "responders" or "nonresponders" based on the measured HoxB13:IL17BR expression ratio, (iii) measuring the HoxB13 and IL17BR expression levels in a sample obtained from an ER+ breast cancer patient and determining the ratio of HoxB13:IL17BR mRNA, and (iv) classifying the patient as a tamoxifen responder or a tamoxifen non-responder by comparing the measured HoxB13:IL17BR ratio to the cutoff ratio, wherein a ratio higher than the cutoff ratio indicates a tamoxifen non-responder and a ratio lower than the cutoff ratio indicates a tamoxifen non-responder. It is not clear from the original disclosure that that an average HoxB13:IL17BR ratio was calculated from the average HoxB13 and IL17BR mRNA expression levels in ER+ breast cancer cells obtained from human breast

cancer patients that responded to treatment with an antiestrogen agent and from human breast cancer patients that did not respond to treatment with the antiestrogen agent as required by the instant claims. Accordingly, claims 14, 16, 18-23, 25, 27-31, 52-55, 62, 63, 69, and 71-73 have been rejected for incorporating new matter.

Claim Rejections - 35 USC § 112, 1st paragraph (Scope of Enablement)

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14, 16, 18-23, 25, 27-31, 52-55, 62, 63, 69, and 72 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method comprising the use of the HoxB13:IL17BR expression level ratio measured in an ER+ breast cancer cell sample obtained from a human subject known to have ER+ breast cancer to identify a human ER+ breast cancer patient as likely to be responsive to letrozole, does not reasonably provide enablement for methods comprising the use of the HoxB13:IL17BR expression level ratio measured in an ER+ breast cancer cell sample obtained from a human subject known to have ER+ breast cancer to identify a human ER+ breast cancer patient as likely to be responsive to any other aromatase inhibitor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: (1) the nature of the invention, (2) the breadth of the claims, (3) guidance in the

specification, (4) the presence or absence of working examples, (5) state of the art, (6) predictability in the art, and (7) the amount of experimentation necessary and the relative skill levels of those in the art.

Nature of the Invention:

Claims 14, 16, 18-22, 52, 53, 62, and 72 are drawn to a method of determining the clinical outcome of a human subject afflicted with ER(+) breast cancer if treated with an aromatase inhibitor based on the observed ratio of HoxB13 and IL17BR RNA expression levels. Claims 23, 25, 27-31, 54, 55, 63, and 69 are drawn to a method for predicting an ER(+) breast cancer patient's responsiveness to treatment with an aromatase inhibitor based on the observed HoxB13:IL17BR mRNA expression level ratio. The claimed methods are classified in the unpredictable arts of chemistry and biology.

Breadth of the claims:

The claims are very broad in scope. The methods of claims 14, 18-23, 27-31, 52-55, 62, and 63 encompass determining an outcome for a human ER+ breast cancer subject if treated with **any** aromatase inhibitor based on the observed HoxB13:IL17BR mRNA expression level ratio measured in an ER+ breast cancer cell sample obtained from the breast cancer subject. Claims 16 and 25 limit the aromatase inhibitors to non-steriodal aromatase inhibitors. Claims 69 and 72 further limit the non-steriodal aromatase inhibitors to letrozole, vorozole, and anastrozole. As evidenced by Bruggemeier et al. (Endocrine Reviews (2005) 26(3): 331-345; newly cited),

aromatase inhibitors and non-steriodal aromatase inhibitors form a very large genus of compounds with widely differing chemical structures and reaction mechanisms (pages 334-339).

Guidance of the specification and Working Examples:

The specification generically teaches that the ratio of HoxB13 and IL17BR mRNA expression levels can be used to determine a risk of cancer recurrence, predict clinical outcome, and predict the responsiveness of any human subject to treatment with any antiestrogen agent (see, for example, pages 9-12, 15-16, and 55). The specification provides only minimal guidance as to the use of the observed HoxB13:IL17BR ratio to assess the potential responsiveness of ER(+) breast cancer patients to aromatase inhibitor treatment, however. The specification identifies letrozole and anastrozole as aromatase inhibitors that can be useful in treating hormonally-responsive breast cancer that is resistant to tamoxifen treatment (page 4). The specification also teaches that the aromatase enzyme provides a large amount of estrogen, and, as such, is a target for inhibitory pharmaceuticals in hormonally-responsive breast cancer (page 14). The specification further teaches that anastrozole, letrozole, and vorozole, which are non-steriodal aromatase inhibitors, inhibit the function of the aromatase enzyme by binding to the heme prosthetic group of the enzyme (page 14), whereas the steroidal aromatase inhibitors inhibit aromatase function by binding directly to the enzyme (page 14).

The working examples only examine the ability of the HoxB13:IL17BR mRNA expression level ratio to assess the potential esponsiveness of human ER(+) breast cancer patients to tamoxifen treatment. They do not contain any discussion or evidence to suggest that

the results obtained for tamoxifen treatment would extend to any other treatment for hormonally-responsive breast cancer, such as the claimed aromatase inhibitors.

State of the Art and Unpredictability in the Art

In general, the art is underdeveloped with respect to the use of gene expression profiles to predict the responsiveness of breast cancer patients to a particular type of treatment. The prior art does not teach the using the ratio of HoxB13:IL17BR mRNA expression levels to assess the potential responsiveness of human ER(+) breast cancer patients to aromatase inhibitor therapy, and, thereby, predict a clinical outcome.

The art does suggest, however, that the claimed methods, which correlate gene expression results with a phenotypic quality, are associated with a high degree of unpredictability. For example, Wu (Journal of Pathology (2001) 195(1):53-65; cited previously) teaches that gene expression data must be interpreted in the context of other biological knowledge, involving various types of "post genomics" informatics, including gene networks, gene pathways, and gene ontologies (page 53, left column). The reference indicates that many factors may be influential to the outcome of data analysis, and teaches that expression data can be interpreted in many ways. The conclusions that can be drawn from a given set of data depend heavily on the particular choice of data analysis. Much of the data analysis depends on such low-level considerations as normalization and such basic assumptions as normality (page 63).

Mello-Grand et al. (Breast Cancer Research and Treatment (2010) 121: 399-411; newly cited) screened a cohort of ER(+) breast cancer patients to undergoing treatment with an aromatase inhibitor (anastrozole) to determine whether gene expression profiling could be used

to predict a patient's responsiveness to the aromatase inhibitor therapy (abstract and pages 402-407). Mello-Grand identified 54 genes whose expression levels were correlated with responsiveness to anastrozole, but only five of these genes were also able to predict responsiveness to letrozole, which is a very similar aromatase inhibitor (see abstract, page 406, and page 409). These results of Mello-Grand suggest that, in the absence of testing, it is unpredictable whether a particular gene expression profile will be correlated with responsiveness to a particular aromatase inhibitor.

Similarly, Miller et al. (Journal of Clinical Oncology (2009) 27: 1382-1387; newly cited) screened a cohort of ER(+) breast cancer patients to undergoing treatment with an aromatase inhibitor (letrozole) and identified genetic parameters that could be used to predict a patient's responsiveness to the aromatase inhibitor therapy (abstract and pages 1383-1385). Miller also teaches that the results of the study are not necessarily extendable to other breast cancer therapies, stating (see page 1385):

> To our knowledge, these data represent the first published genetic profile discriminating for response to an aromatase inhibitor. Jansen and colleagues[16] have published different gene expression signatures for response of advanced breast cancer to the antiestrogen, tamoxifen, based on pretreatment profiling in primary tumors. This suggests that predictive molecular profiles will differ according to the modes of endocrine therapy used and/or the setting in which they are assessed. The current profile also has minimal coincidence with published signatures associated with lack of response to chemotherapy.[17]

Based on these teachings in the art, it is clear that the claimed methods are associated with a high degree of unpredictability.

Quantity of Experimentation

The quantity of experimentation required in this case is immense, because it would require significant study and experimentation including trials with large numbers of patients to determine that the HoxB13:IL17BR RNA expression ratio recited in the claimed methods can be used to reliably assess an ER(+) patient's likelihood of being non-responsive to therapy with even a single aromatase inhibitor. The ability of the HoxB13:IL17BR mRNA expression level ratio to reliably predict responsiveness to each different aromatase inhibitor encompassed by the claims would have to be evaluated independently using the large quantity of experimentation described by Ma et al. (Cancer Cell (2004) 5: 607-616; cited previously) (see pages 611-613), Mello-Grand (see pages 400-402, and Miller (pages 1382-1383) and with no guarantee of success. As discussed above, each of these references focused their attention upon one, in the case of Ma and Miller, or two, in the case of Mello-Grand, specific anti-estrogen agents and conducted extensive validation experiments to determine that a particular gene expression profile was correlated with responsiveness to the anti-estrogen agent (see pages 611-613 of Ma, pages 400-402 of Mello-Grand, and pages 1382-1383 of Miller). Also, none of these references teaches or suggests that the ability of a particular gene expression signature to predict responsiveness to one anti-estrogen agent is extendable to any other anti-estrogen agent. Rather, as discussed above, the Miller and Mello-Grand references suggest that different genes will predict responsiveness to different breast cancer therapeutics. Thus, based on these teachings in

the art, the quantity of experimentation required to practice the full scope of the claimed methods would be extremely large, such that it would constitute an inventive undertaking.

The Level of skill in the art

The level of skill in the art is deemed to be high.

Conclusion

Given the complex nature and broad scope of the claimed invention, the underdeveloped state of the art at the time of filing, the unpredictability inherent in the claimed invention, and the limited nature of the disclosure, the ordinary artisan would be required to conduct a very large quantity of non-routine and unpredictable experimentation to practice the full scope of the claimed methods. Accordingly, the methods of claims 14, 16, 18-23, 25, 27-31, 52-55, 62, 63, 69, and 72 do not comply with the enablement requirement of 35 U.S.C. 112, first paragraph.

Response to Arguments

8. Applicant's arguments filed on March 21, 2010 have been fully considered, and they are persuasive, in part.

Claim Objections

Applicant argues that the claim amendments have obviated the previously made objections to claims 12, 35, 49, 50, 52-57, 59, 60, and 67-70 (pages 7-8). This argument was persuasive, and, accordingly, the previously made objections have been withdrawn.

Rejection under 35 U.S.C. 112, second paragraph

Applicant argues that the claim amendments have obviated the previously made rejection of claims 38, 42, 49, 50, 52-57, 60-63, and 70 under 35 U.S.C. 112, second paragraph (page 8). This argument was persuasive, and, accordingly, the previously made objections have been withdrawn. New grounds of rejection under 35 U.S.C. 112, second paragraph, which were necessitated by the claim amendments are presented above, however.

Rejection under 35 U.S.C. 112, 1st paragraph (new matter)

Applicant argues that the rejection of claims 14, 16, 18-23, 25, 27-31, 52-55, 62, 63, 69, and 71-73 under 35 U.S.C. 112, first paragraph (new matter) should be withdrawn, because Examples 3-4 and Figures 3, 6, and 7 of Application Serial No. 10/727,100, to which the instant application claims priority and which has been expressly incorporated by reference, provide adequate support for determining a mean HoxB13:IL17BR ratio and using the mean ratio as a comparison point for HoxB13:IL17BR expression levels determined from ER+ breast cancer cells obtained from a human patient (see pages 9-10). This argument was not persuasive, because, although, as discussed by Applicant at pages 9-10 of the response, the zero point on the Y-axis of Figure 7 of the '100 application represents the mean ratio of HoxB13:IL17BR mRNA expression levels, it does not appear from the disclosure that the mean ratio was used as a comparison point as required by the claims. Rather, based on the disclosure in Example 4 of the '100 application, it would appear that a value other than the zero point of the Y-axis of Figure 7 was used as the comparison point (see page 72 and Figure 7, where a value of -0.22 or 0.22 was used as the point of comparison). There is also no discussion of the mean HoxB13:IL17BR

mRNA expression level ratio in either the instant application or the incorporated '100 application or using the mean expression level ratio as a comparison point for classifying test samples. As a result, the original disclosure does not appear to provide adequate support for the claimed methods in which the mean ratio is used to classify patients as likely or unlikely to respond to treatment with an aromatase inhibitor. Since Applicant's arguments were not persuasive, the rejection has been maintained.

Rejection under 35 U.S.C. 112, 1st paragraph (enablement)

The previously made rejection of claims 6-8, 10-16, 18-25, 27-38, 42, 49, 50, 52-63, 68, and 70 under 35 U.S.C. 112, first paragraph (lack of enablement) has been withdrawn in view of the claim amendments, which substitute tamoxifen treatment for treatment with an aromatase inhibitor. New grounds of rejection under 35 U.S.C. 112, first paragraph have been set forth above in view of the claim amendments.

Applicant presents arguments and evidence that is relevant to the new rejection. These arguments and evidence have been fully considered, but they were not persuasive. Applicant describes an experiment conducted by the inventors in which the HoxB13:IL17BR ratio was determined and analyzed in a group of ER+ breast cancer patients about to undergo treatment with letrozole, which is an aromatase inhibitor (page 11). The data presented on page 11 suggests that a HoxB13:IL17BR ratio that is higher than the average ratio is correlated with non-responsiveness to letrozole, but, as discussed in the new rejection above, the data presented in the response, the prior art, and the guidance in the specification does not reasonably provide

enablement for the full scope of the claimed methods, which encompass a very large and variable genus of aromatase inhibitors.

Rejection under 35 U.S.C. 112, 1st paragraph (written description)

The previously made rejection of claims 6-8, 10-16, 18-25, 27-38, 42, 49, 50, 52-63, 68, and 70 have been under 35 U.S.C. 112, first paragraph (written description) has been withdrawn in view of the claim amendments and in view of the fact that, upon further consideration, the claims comply with the written description requirement of 35 U.S.C. 112, first paragraph. Accordingly, Applicant's arguments filed on page 12 have been considered, but they are moot in view of the withdrawal of the rejection.

Rejection on the ground of non-statutory obviousness-type double patenting

Applicant argues that the previously made rejection of claims 6-8, 10-16, 18-25, 27-38, 42, 49, 50, 52-63, and 67-70 on the ground of non-statutory obviousness-type double patenting citing US 7,504,214 has been obviated by the claim amendments (page 13). This argument was persuasive, and, accordingly, the rejection has been withdrawn.

Provisional rejection on the ground of non-statutory obviousness-type double patenting

Applicant argues that the previously made provisional rejection of claims 6, 7, 9-15, 17-22, 32, 34-38, 42, and 58-62 on the ground of non-statutory obviousness-type double patenting citing copending Application Serial No. 11/089,097 has been obviated by the claim amendments

(pages 13-14). This argument was persuasive, and, accordingly, the provisional rejection has been withdrawn.

Conclusion

9. No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANGELA BERTAGNA whose telephone number is (571)272-8291. The examiner can normally be reached on M-F, 9- 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Angela M Bertagna/
Examiner, Art Unit 1637